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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/29/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/771,151	Applicant(s) Basic	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

4) Claim(s) 1-18 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-18 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 20) Other: _____

U. S. Patent and Trademark Office
PTO-326 (Rev. 9-00)

Office Action Summary

Part of Paper No. 6

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DETAILED ACTION

The correction of inventor's name dated 5-21-01 is acknowledged.

Claims included in the prosecution are 1-18.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants are claiming a specific method of preparation of liposome and therefore, claim 1 should recite the individual steps. Claim 1 just recites selecting the compound and the liposomal sizes, but does not recite how the supersaturated solution of the compound is entrapped in the liposomes. 'a condition' is indefinite since it is unclear what the condition is and where the condition occurs. Is it before or after the entrapment? Also unclear is according to the claim 1, lines 4-5 there is no precipitation of the supersaturated solution; that means the compound is still in a dissolved form. What is then being conveyed by 'capable of exhibiting at least a two-fold increase in response to a condition'? How can size

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of the liposomes by itself does not cause the precipitation of the compound and how is the size selected?

The examiner suggests ‘comprises’ wherever ‘includes’ (including) is recited in the claims.

Claim 1 already recites a supersaturated state of the compound. What is being conveyed in claim 10?

Does it mean that the compound is not in a supersaturated state after entrapment as recited in claim 11?

Claims 10 and 14-15 are indefinite since these recite ‘composition according to claim 1’; however, claim 1 is a method claim.

‘Concentrated’ in claim 16 is a relative term and hence indefinite. The examiner suggests concentration ranges. Furthermore, it is unclear whether ‘concentrated’ and ‘supersaturated’ are the same in this context; both terms are recited in the same claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 1-6, 10-13, 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0177 223.

EP discloses a method of preparation of liposomes containing a supersaturated solution of a biologically active compound (note the abstract, page 10, lines 4-5, Examples and claims).

5. Claims 1-6, 8-13, 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 551 169.

EP discloses a method of preparation of liposomes containing a supersaturated solution of a water soluble drug (note the abstract, Example 3 and claims).

6. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/07409.

WO 98 discloses a method of preparation of liposomes containing supersaturated solution of an active compound. The liposomes further contain a hydrophilic polymer (PEG) (note the abstract, page 2 line 15 through page 3, line 24, page 6, lines 14-26, page 12, lines 4-21, Example 3 and claims).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the

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prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 7, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of EP 0 177 223 or EP 0 551 169 in combination with Woodle (5,013,556) of record.

What is lacking in either of the EP references is the inclusion of a hydrophilic polymer in the liposome compositions.

Woodle discloses that the inclusion of a hydrophilic polymer enhances the circulation time of the liposomes (note the abstract).

The inclusion of a hydrophilic polymer in the liposomes of EP references would have been obvious to one of ordinary skill in the art because it enhances the circulation time of the liposomes as taught by Woodle.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *T.K. Page*, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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**Any inquiry of a general nature or relating to the status of this application should
be directed to the Group receptionist whose telephone number is (703)308-1235.**



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 21, 2002